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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/993,363 | 11/14/2001 | Philip G. Ashton-Rickardt | ARCD:382US | 5741 |
| 7590 Priya D. Subramony Fulbright & Jaworski L.L.P. Suite 2400 600 Congress Avenue Austrin, TX 78701 | | | EXAMINER WEHBE, ANNE MARIE SABRINA | |
| | | | ART UNIT 1633 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | | MAIL DATE | DELIVERY MODE |
| 3 MONTHS | | | 01/30/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/993,363

Applicant(s)

ASHTON-RICKARDT ET AL.

Examiner

Anne Marie S. Wehbe

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 15, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-33, 35, 37-40, 42-44, 48-50, 61-63 and 65-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-33, 35, 37-40, 42-44, 48-50 and 74 is/are allowed.
- 6) ☒ Claim(s) 26-29, 61-63, 65, 67, 71, 72 is/are rejected.
- 7) ☒ Claim(s) 66, 68-70 and 73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response under 37 CFR 41.52 received on 11/15/06 has been entered. Claims 34 and 64 have been canceled by this amendment. Claims 26-33, 35, 37-40, 42-44, 48-50, 61-63, and 65-74 are currently pending in the instant application. Please note that the examiner of record and the art unit have changed for this application. See the last page of this office action for details.

Prosecution History

The decision by the Board of Patent Appeals and Interferences mailed on 9/20/06 reversed the rejection of claims 26-35, 37-40, 42-44, 48-50, and 61-74 made by the previous examiner of record under 35 U.S.C. 112, first paragraph, for lack of enablement, and vacated the rejection of claims 26-35, 37, 42-44, 48-50, 61-65, 67, and 71-73 under 35 U.S.C. 112, first paragraph, for lack of written description.

In addition, the Board, under the provisions of 37 CFR 41.50(b), entered a new ground of rejection against claims 34 and 64 under 35 U.S.C. 112, first paragraph, for lack of written description based on new matter.

Applicant's cancellation of claims 34 and 64 render the Board's rejection of these claims moot.

However, the previous examiner of record made an election of species requirement on the generic claims to which the applicant elected the species HIV as the viral infection, and PI9 as
9/21/2007

Art Unit: 1633

the species of granzyme inhibitor, see the non-final office action mailed on 3/19/03. The examiner reiterated this species election requirement on page 2 of the Final office action mailed on 9/10/03 and stated that the claims were examined to the extent that these encompass the elected species. However, it is in fact noted that the examiner did not withdraw from prosecution claims 69 and 73 which are not drawn to the elected species. While the Board noted the election of the species PI9 and HIV on page 5 of the Decision, the Board assumed that since the rejections for enablement and written description were directed to serpins and viruses in general that the broader aspects of the claimed invention had been examined by the previous examiner of record.

The new examiner of record, however, could not determine whether the breadth of the claimed invention for serpins and viral infections had in fact been searched and examined for prior art under 35 U.S.C. 102 and 103. Prosecution in this application has therefore been reopened in order to withdraw the species election requirement made by the previous examiner and to determine patentability of the broad claims under 35 U.S.C. 102 and 103.

Prosecution on the merits of this application is reopened on claims 26-29, 61-63, 65, 67, and 71-72, considered unpatentable for the reasons indicated below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1633

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-29, 61-63, 65, 67, and 71-72 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0127698 A1 (9/12/02), hereafter referred to as Lynn et al., as evidenced by Cullen (2001) Nature, Vol. 7(1), 20-21. The applicant claims methods for enhancing or inducing immunity to a viral infection comprising expressing a serpin or a serpin mimetic in a cytotoxic T-lymphocyte of a subject by introducing an expression construct comprising a DNA segment encoding the serpin or serpin mimetic under the control of a promoter active in the cytotoxic T-lymphocyte. The applicant further claims said methods wherein the enhancing or inducing comprising increasing the number of CTL memory cells, or augmenting CTL function or development. In addition, the applicant claims said methods wherein the expression construct is a viral expression construct, or more particularly a retrovirus or adenovirus, and wherein the viral infection is HIV.

Lynn et al. teaches methods of treating HIV infection in a patient by introducing a DNA molecule encoding a serpin to a cell susceptible to HIV infection (Lynn et al., abstract, page 15, claims 19-23, and page 12, column 2). Lynn et al. further teaches the use of viral vectors such as retroviral and adenoviral vectors to express the serpin in cells in the patient, and also teaches that the vectors include suitable promoter for expression in the host cells, such as the SV40 promoter (Lynn et al., page 12, particularly paragraphs 0125 and 0126). The instant claims as written indicate that the promoter must be active in CTL. The SV40 promoter is just such a promoter.

Art Unit: 1633

Please note that the instant claims do not limit the promoter to cell specific promoter that is only active in CTL. Further, while Lynn et al. does not specifically teach the expression of serpin in CTL, Lynn et al. does teach that the DNA encoding a serpin is introduced and expressed in a “cell susceptible to HIV infection”. Cullen et al. provides evidence that at the time of filing, the skilled artisan would have recognized that CD8 T lymphocytes, i.e. cytotoxic T lymphocytes, are susceptible to infection with certain strains of HIV (Cullen, pages 20-21).

While Lynn et al. teaches the exact same methods steps as the applicant’s claimed methods, i.e. introducing an expression construct comprising a DNA segment encoding a serpin under the control of a promoter active in CTL in patients with HIV viral infection, Lynn et al. does not teach the specific effect resulting from the introduction of serpin DNA recited in applicant’s claims. However, it is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. *In re Woodruff*, 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed.Cir. 1990); *In re Swinehart*, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and *Ex Parte Novitski*, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993). The MPEP also states that “when the claim recites using an old composition or structure and the ‘use’ is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F. 2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978)”. MPEP 2112.02. Thus, by teaching the use of the same composition and same methods steps as the instant claims, Lynn et al. anticipates the instant claims as written.

Claims 30-33, 35, 37-40, 42-44, 48-50, 66, 68-70, and 73-74 are free of the prior art of record. The closest prior art, Lynn et al. cited above, does not teach or suggest the introduction of

Art Unit: 1633

cytotoxic T lymphocytes comprising an expression vector encoding a serpin to a subject with HIV or any other viral infection. Further, neither Lynn et al. nor the remaining prior art of record teaches or provide specific motivation for expressing PI9 or SPI6 in CTL to induce immunity to a viral infection.

Allowable Subject Matter

Claims 66, 68-70, and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 30-33, 35, 37-40, 42-44, 48-50, and 74 are allowed.


Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., Art Unit 1633, whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

Art Unit: 1633

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé


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PRIMARY EXAMINER

